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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,190	MATSUDA ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/7/05*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,32,34-40,42-49 and 53-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,32,34-40,42-49 and 53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks filed 9/7/05 is acknowledged. Claims **31-32, 34-40, 42-49, and 53-59** are pending in this application. Claims 1-30, 33, 41, and 50-52 stand cancelled.

Claim Objections

The objection of claims 42-49 is withdrawn in view of the amendments of 9/7/05.

Claim Rejections - 35 USC § 112

The rejection of claims 31-32, 34-40, 42-49, and 53-59 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments of 9/7/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-32, 36, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754).

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia and hyperphsophatemia. See abstract and column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, water, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, etc and can be coated to protect the composition from disintegration. See column 3, lines 35-60. Further, the disclosure of US 5,496,545 and 5,487,888 are incorporated by reference. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier.

It should be noted that although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP.

Holmes-Farley et al does not exemplify the tablet formulation.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Holmes-Farley et al and utilize a tablet formulation containing the phosphate-binding polymer. One would have been motivated to do so with the expectation of similar results since the prior art clearly teaches that the tablets are suitable form for administering the instant polymers. Thus, one would be motivated to utilize the dosage form of choice depending on the desired type of administration. Secondly, Holmes-Farley suggests the use of microcrystalline cellulose as a suitable carrier; therefore a skilled artisan would have been motivated to utilize a conventional excipient such as microcrystalline cellulose with a reasonable expectation of success.

Response to Arguments

Applicant's arguments filed 9/7/05 have been fully considered but they are not persuasive.

Applicant argues that the Rule 132 declaration of 3/1/05 demonstrates that tablets only containing the phosphate-binding polymer exhibit stickiness. Applicant argues that the tablet containing the phosphate-binding polymer and HPC-L or HPMC exhibits stickiness. Applicant argues it is not the hardness that is critical to the unexpected tablets but rather the combination of particles of an average particle size of no more than 400 microns, at least 90% being particles no larger than 500 microns, and having a true specific gravity of 1.20-1.22 and a water content of 1-14%, and at least one of crystalline cellulose or substituted hydroxypropyl cellulose. It is this combination of factors plus a hardness of over 6.2 that produces an unexpectedly superior tablet. Applicant argues that the examiner concedes the Holmes-Farley does not teach the instant specific gravity and properties or a tablet formulation.

Applicant's arguments filed 9/7/05 have been fully considered but they are not persuasive. Firstly, for the record, the examiner has not stated that the phosphate polymer particles taught in Holmes-Farley et al do not have the instant properties. In fact, the examiner has repeatedly stated that although the prior art has not explicitly stated that the phosphate polymers have the instant properties, "it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses (note applicant's remarks of 11/20/03) the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP."

The "mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; [the] Patent Office can require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; this burden of proof is applicable to product and process claims reasonably considered as possessing allegedly inherent characteristics." In re Best 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The examiner notes that the applicant has not provided any evidence to rebut the examiner's position.

Secondly, the examiner points out that that Holmes-Farley suggests the use of a tablet. The examiner further points out that a reference need not exemplify all embodiments to suggest

or anticipate an invention. Although Holmes-Farley exemplifies a capsule, disclosed examples and preferred embodiments do not constitute a teaching away form the broader disclosure or nonpreferred embodiment". In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

The examiner has made the rejection under obviousness due to the fact to applicant's limitation of microcrystalline cellulose or l-HPC in the tablet. However, Holmes-Farley suggests microcrystalline cellulose as a suitable carrier (Holmes-Farley incorporates the disclosure of US 5,496,545 and 5,487,888. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier). It should be noted that when a reference is incorporated by reference, the information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. See MPEP 2163.07(b). Further, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The applicant argues that microcrystalline cellulose (MCC) results is a tablet that is less sticky and this is unexpected; however the examiner points out that this is a known feature of MCC. US 3,146,168 cited as art of interest discloses that microcrystalline cellulose has superior compressibility, cohesive strength, and **is less tacky and sticky**. See column 5, lines 6-10 and 35-74. Thus, the prior art actually teaches applicant's "unexpected result" when utilizing microcrystalline cellulose.

Claims 34-35, 39-40, 42-46, 49 and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Chen et al (5,225,204).

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia and hyperphosphatemia. See abstract and column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, water, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, etc and can be coated to protect the composition from disintegration. See column 3, lines 35-60. Further, the disclosure of US 5,496,545 and 5,487,888 are incorporated by reference. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier.

It should be noted that although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP.

Holmes-Farley et al does not expressly teach the compression of the granules into a tablet form, the use of l-HPC, or the weight percent of microcrystalline cellulose.

Chen et al teach a stable dosage form of levothyroxine. Chen teaches conventional tabletting aids include HPC, HEC, L-HPC, microcrystalline cellulose, and lubricants,. Chen teaches the process of making a tablet wherein the active agent, 120g microcrystalline cellulose, 10g L-HPC, and a magnesium stearate lubricant are combined and compressed into a tablet form with a hardness of 14-19kp. See examples.

Further, it would have been ordinary skill in the art at the time the invention was made to look to the guidance provided Chen and formulate Holmes-Farley's phosphate-binding polymers into a tablet. One would have been motivated to look to Chen with a reasonable expectation of success since Chen teaches the process of making a tablet with the instant conventional excipient, microcrystalline cellulose and Holmes-Farley not only suggests the use of tablet formulations but also suggests the use of microcrystalline cellulose as a carrier.

With regard to the limitations of claims 54-59, it is the examiner's position that since the prior art teaches the same phosphate binder and the same excipient (microcrystalline cellulose) the weight loss would be the same absent evidence to the contrary.

Response to Arguments

Applicant argues that Chen's use of microcrystalline cellulose and L-HPC has nothing to do with producing non-sticky tablets. Applicant argues that Chen teaches tabletting aids including HPC, HEC, L-HPC, and microcrystalline cellulose, and does not specify that one is disclosure of additives for better than the others. In fact, the MATSUDA declaration shows that HPC-L and HPMC produce sticky tablets, and there is nothing in Chen that would lead one skilled in the art to choose only crystalline cellulose or L-HPC.

Applicant's arguments filed 9/7/05 have been fully considered but they are not persuasive. Firstly, the examiner points out that Chen is not relied upon to teach the use of microcrystalline cellulose (MCC) per se since Holmes-Farley suggests the use of MCC. Rather, Chen is relied upon to teach the instant weight percent of MCC and the process of making the tablet. Thus, applicant's argument that Chen teaches the use of MCC for a different reason is moot. Chen teaches MCC is a conventional excipient. Chen clearly teaches the preference of MCC since the examples utilize MCC.

Applicant argues that the examiner is relying on hindsight reasoning. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In instant case, applicant arguments of hindsight are based on premise that Holmes-Farley does not teach or suggest the use of MCC; however Holmes-Farley does teach the use of MCC as a carrier. The examiner relies on Chen to demonstrate that the instant excipients have been conventionally used in the instant amount prior to the instant invention.

Claims 37 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Chen et al (5,225,204) in further view of Nakajima (3926817).

The teachings of Holmes-Farley and Chen have been discussed above.

The references do not teach the instant lubricant: hardened oil.

Nakajima teaches stearic acid, magnesium stearate, and hydrogenated castor oil have been widely employed in various pharmaceutical preparations. See column 2, lines 50-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize the instant hydrogenated oil in place of Chen's magnesium stearate. One would have been motivated to do so since Nakajima teaches the instant lubricant and the prior art's magnesium stearate are both utilized as glidants in pharmaceutical compositions. Therefore, it is prima facie obvious to substitute one functional equivalent for another functionally equivalent agent with the expectation of success.

Response to Arguments

Applicant argues that Nakajim adds nothing to the teachings of Holmes Farley. Applicant argues there is nothing in the cited patents that would lead a skilled artisan to formulate a tablet comprising the phosphate binding polymers. Applicant argues that Nakajima does not teach certain additives can make a non-sticky tablet.

Applicant's arguments filed 9/7/05 have been fully considered but they are not persuasive. The examiner has responded to the applicant's "novelty of making a tablet preparation". The examiner points out that Nakajima is relied upon to teach the instant lubricant. Applicant has not provided any unexpected results associated with the use of the instantly claimed lubricant and thus this argument is moot.

Claims 31-32, 34, 36, 39-40, 42, 49, and 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Yaginuma et al (5,574,150) or Battista (3,146,168).

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See abstract and column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, water, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, etc and can be coated to protect the composition from disintegration. See column 3, lines 35-60. Further, the disclosure of US 5,496,545 and 5,487,888 are incorporated by reference. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier.

It should be noted that although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP.

Holmes-Farley et al does not exemplify the tablet formulation. Although, Holmes-Farley suggests the use of microcrystalline cellulose, the excipient is not exemplified.

Yaginuma et al disclose an improved microcrystalline cellulose with high compactability. Yaginuma discloses the *conventional and wide use* of microcrystalline cellulose in the art since it

exhibits high safety, a relatively high compactability and a relatively excellent rate of disintegration. Further, Yaginuma teaches the prior art disclosing the use of microcrystalline cellulose to increase strength of tablets. See column 1, lines 16-40. However, Yaginuma teaches the prior art's microcrystalline cellulose have disadvantages in that when the compactability is high, the rate of disintegration is lowered and when the rate of disintegration is high, the compactability is low. However, Yaginuma teaches an improved microcrystalline cellulose with both high compactability and disintegration. See column 3, lines 30-37. Further, the reference teaches the inventive microcrystalline cellulose may be used in a limited amount to make a small tablet and yet provide the same properties. See column 15, lines 25-32. Yaginuma teaches tablets require at least 4 kgf (4kp) breaking strength and the inventive microcrystalline cellulose provides a strength of 10 kgf (10kp) or mere. See column 15, line 40 to column 14, lines 15.The examples teach combining inventive microcrystalline cellulose (19%) with an active, and lactose and compressing the mixture.

Battista teaches manufacturing pharmaceutical composition containing crystalline cellulose aggregates. Battista teaches in comparison with prior art excipients such as starch and lactose, the crystalline cellulose provides superior compressibility during direct compression and cohesive power. Further, Battista teaches crystalline cellulose has excellent flow ability and is less tacky and sticky than starch. See column 15. example 16 utilizes 25% of the cellulose powder.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Holmes-Farley and Yaginuma or Battista and select instant microcrystalline cellulose. One would have been motivated to do so since Yaginuma teaches the

state of the art wherein it is known and conventional to use microcrystalline cellulose to increase the strength of a tablet. Moreover, Yaginuma teaches an improved microcrystalline cellulose that not only improves strength to yield a tablet having a hardness of 10 KP but also good disintegration. Battista also teaches crystalline cellulose provide increased compactability (hardness) to pharmaceutical tablets. Therefore, if a skilled artisan desired to increase the strength of tablet, it would have been prima facie to utilize microcrystalline cellulose as the excipient of choice.

With regard to the limitations of claims 54-59, it is the examiner's position that since the prior art teaches the same phosphate binder and the same excipient (microcrystalline cellulose) the weight loss would be the same absent evidence to the contrary.

Response to Arguments

Applicant argues that the examiner concedes that the prior art cited does not teach the instant specific gravity and properties. Applicant argues that despite Yaginuma's teaching that microcrystalline cellulose can be used to increase the strength of the tablet, this is not the reason the present invention uses microcrystalline cellulose. Applicant argues that Battista discloses that microcrystalline cellulose is less tacky and sticky than starch but there is nothing in either Yaginuma or Battista that suggests using microcrystalline cellulose with a phosphate-binding polymer would produce unexpectedly superior tablets. Applicant argues that it is not solely the hardness of the tablets that makes them superior but it is also the non-stickiness of the tablets that makes them superior.

Applicant's arguments filed 9/7/05 have been fully considered but they are not persuasive. Firstly, for the record, the examiner has not stated that the phosphate polymer

particles taught in Holmes-Farley does not have the instant properties. In fact, the examiner has repeatedly stated that although the prior art has not explicitly stated that the phosphate polymers have the instant properties, "it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses (note applicant's remarks of 11/20/03) the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP."

The "mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; [the] Patent Office can require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; this burden of proof is applicable to product and process claims reasonably considered as possessing allegedly inherent characteristics." In re Best 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The examiner notes that the applicant has not provided any evidence to rebut the examiner's position.

In response to applicant's argument that applicant utilizes MCC to decrease stickiness versus Yaginuma's reasons for using MCC to increase the strength of the tablet, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would

otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The examiner again points out that Holmes Farley suggests the use of microcrystalline cellulose and Yaginuma's provides a motivation to specifically select MCC as the carrier of choice. The fact that the examiner's motivation to combine the reference is different from applicant's motivation is moot.

With regard to applicant's argument that Yaginuma or Battista do not suggest using microcrystalline cellulose in combination with a phosphate-binding polymer would produce unexpectedly superior tablets, the examiner points out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner points out that Holmes Farley suggests MCC as a suitable carrier and Yaginuma and Battista respectively are secondary references that provide a motivation to specifically utilize MCC. Thus, the fact that the secondary reference does not teach the instant phosphate polymers is moot since the test for obviousness is not that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues Battista discloses cellulose crystallites that have the capacity to absorb aggregates moisture. Applicant argues Battista uses different microcrystalline cellulose than the instant invention. The examiner points out that the instant claims are broadly directed to microcrystalline cellulose without any distinction, therefore the instant scope does not exclude Battista's microcrystalline cellulose.

Claims 35, 37-38, and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Yaginuma et al (5,574,150) or Battista (3,146,168) in further view of Sato et al (5,202,335).

Holmes Farley, Yaginuma, and Battista have been discussed above.

The references do not teach the additional use of instant l-HPC or a lubricant. Further, although Holmes-Farley teaches using a coating, the reference does not specify the type of coating.

Sato et al teach succinic compounds for oral administration. Sato teaches that in molding pharmaceutical compositions into tablet formulations, many conventional carriers known in the art may be used. These carriers include lactose, sucrose, microcrystalline cellulose, etc. Sato also teaches the use of conventional disintegrators such as low-substituted HPC and the use of glidants. The tablets may be coated with a sugar coating, gelatin coating, enteric coating, and film coating, depending on the desired effect. See column 8, lines 54-68. Sato teaches various suitable excipients for the composition that are known in the art. See column 9, lines 1-16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Holmes-Farley et al, Yaginuma or Battista respectively, and Sato et al and further add L-HPC. One would have been motivated to do so since Sato teaches L-HPC is a conventional disintegrant in the tabletting art. Thus, a skilled artisan would have been motivated to utilize instant l-HPC as a disintegrant in the composition to manipulate the disintegration of the tablet. Lastly, a skilled artisan would be motivated to coat the tablet depending on the desired effect of the composition, i.e. a sugar coat for a palatable tablet or a film coat for a smooth, glossy appearance.

Response to Arguments

Applicant argues that Sato never discloses that the succinic acid compounds are sticky when formulated into tablets, so there is no teaching or suggestion for specifically using L-HPC rather than other cellulose compounds to prevent the tablets from becoming sticky and difficult to swallow. Applicant argues that none of the patents cited, alone or in combination, would suggest to one skilled in the art that tablets can be prepared from this particular combination of ingredients having the specific physical characteristics recited.

Applicant's arguments filed 9/7/05 have been fully considered but they are not persuasive. The examiner points out that the fact that Sato's reason for using l-HPC is different from the applicant's or the fact that that the examiner's motivation to is different from applicant's motivation is irrelevant. The examiner points to *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985), "the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-32, and 34-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,383,518 and 6,696,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to similar subject matter.

The instant application is directed to a tablet having a hardness of 6KP and comprising phosphate-binding polymers with particle size of no larger than 500 microns and at least one of crystalline cellulose and l-HPC. The particles have a moisture content of 1-14%. Claim 37 is directed to the use of a hardened oil. Claim 38 is to the tablet having a water-soluble coating.

US '518 is directed to a tablet comprising a phosphate binding polymer having a specific formula and having a particle size of 500 microns or less, and crystalline cellulose and/or l-HPC. Claim 2 is directed to a tablet that comprises phosphate-binding polymers with a moisture content of 1-14% and crystalline cellulose and/or l-HPC. Dependent claims are directed to the use of a hardened oil. Dependent claims are directed to a tablet having water-soluble coating.

US '087 is directed to a tablet with a hardness of 6KP or more comprising phosphate-binding polymers having a specific formula and crystalline cellulose and/or l-HPC. Dependent claims are directed to the use of a hardened oil. Dependent claims are directed to a tablet having water-soluble coating.

The instant application, which does not specify the formula of the phosphate-binding polymer, is directed to the broader scope of US patents '518 and '087. Thus, the instant application fully encompasses the subject matter of the patented claims.

Response to Arguments

Applicant has not argued the merits of this rejection. Therefore, the rejection is maintained.

Conclusion

None of the claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER